MAR 1 3 2012

## 6.0 510(k) Summary

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| **Submitter:** | Medical Designs, LLC<br>1210 W. 18th Street, Suite 104<br>Sioux Falls, South Dakota 57104 |
| **Contact Person:** | Kristi Vondra<br>Vice President of Operations<br>Telephone: (605) 275-1032<br>Fax: (605) 335-3734 |
| **Date Prepared:** | September 8, 2011 |
| **Trade Name:** | Asfora Bullet Cage™ System, Intervertebral Body Fusion Device |
| **Classification:** | Class II<br>Intervertebral Body Fusion Device<br>21 CFR 888.3080 |
| **Product Code:** | MAX |
| **Predicate Device(s):** | The subject device is equivalent to the following devices:<br>• K090048, Asfora Bullet Cage System<br>• P950019/S9 Ray TFC Threaded Fusion Cage (down-classified to Class II) |
| **Device Description:** | The Asfora Bullet Cage (ABC) is a threaded titanium alloy interbody fusion device (cage) with a threaded titanium end cap.<br>The ABC is a threaded, self-tapping, bullet-shaped, hollow-body, device designed to immobilize adjacent vertebrae and promote arthrodesis (fusion) across the disc space. The Asfora Bullet Cage is available in ten sizes: 5 diameters (10mm, 12mm, 14mm, 16mm, and 18mm) and 2 lengths (21mm or 25mm). |
| **Intended Use:** | The Asfora Bullet Cage® is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) and instability in the lumbar spine at one or two contiguous levels from L2 to S1. DDD for lumbar systems is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The ABC cage devices are used with autogenous bone graft. Patients should be skeletally mature and have had at least six (6) months of non-operative treatment prior to implant. When implanted via a posterior (PLIF, TLIF) approach, this device should be used with supplemental fixation.. |
| **Functional and Safety Testing:** | No significant changes to the design of the device were made. Risk assessment was performed which concluded no additional testing was required. |
| **Conclusion:** | Medical Design, LLC considers the device name to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medical Designs, LLC
% Ms. Kristi Vondra
VP of Operations
1210 W. 18th Street, Suite 104
Sioux Falls, South Dakota 57104

MAR 13 2012

Re: K112648
Trade/Device Name: Asfora Bullet Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: February 17, 2012
Received: February 21, 2012

Dear Ms. Vondra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 5.0 Indications For Use Statement

510(k) Number: K112648

Device Name: Asfora Bullet Cage System

Indications for Use:

The Asfora Bullet Cage® is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) and instability in the lumbar spine at one or two contiguous levels from L2 to S1. DDD for lumbar systems is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The ABC cage devices are used with autogenous bone graft. Patients should be skeletally mature and have had at least six (6) months of non-operative treatment prior to implant. When implanted via a posterior (PLIF, TLIF) approach, this device should be used with supplemental fixation.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112648